DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 17, 2015

Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasa
% Michael Scott
President
ST&T Research
2237 Chestnut Street
San Francisco, CA 94123

Re: K140506
Trade/Device Name: Joy Drops™ Natural Personal Lubricant Gel
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 13, 2015
Received: March 17, 2015

Dear Michael Scott,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K140506

Device Name: JoyDrops® Natural Personal Lubricant Gel

Indications For Use:

JoyDrops® Natural Personal Lubricant Gel is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use __X_____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ST&T Research Departments:

PRODUCT DEVELOPMENT & CLINICAL RESEARCH DRUG-

DEVICES-COSMETICS-SUPPLEMENTS-FOOD/BEVERAGE US

AGENT FDA-FTC-EPA-CUSTOMS - & GRAS REGISTRATION

LABELING & INTERNATIONAL REGULATORY CONSULTATION

PRE & POST- MARKET CONSUMER PRODUCT USE RESEARCH

☐*INFORMATION& CONSULTING:* ***800-869-4636***

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS [21 CFR 807.92(c)]

Date Revised: April 17, 2015

510(k) Number: K140506

Submitter:

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Device (807.92(a)(2): Trade or Proprietary Name: **JoyDrops® Natural Personal Lubricant Gel**
Common or Usual Name: Personal Lubricant
Classification Name: Condom
Product Code: NUC
Regulation Number: 21 CFR 884.5300
Device Class: Class II

Predicate Device [807.92(a)(3): Walgreens Personal Lubricating Jelly (K080978)

Indications for Use

JoyDrops® Natural Personal Lubricant Gel is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Device Description
JoyDrops® Natural Personal Lubricant Gel is a water-based personal lubricant gel that is contained in a 3.38 fluid ounces (100 mL) polymer container with a pump dispenser.

Directions for Product Use
Remove the cap of the JoyDrops® Natural Personal Lubricant Gel, and then twist the pump to open. Gently squeeze the tube to obtain the desired amount of lubricant. A 1 to 2 inch strip should be sufficient. May be applied directly onto the condom or onto the penis or into the vagina.

Product Performance and Condom Compatibility
JoyDrops® Natural Personal Lubricant Gel has been tested for performance by subjecting it to Condom Compatibility testing. Condom Compatibility was tested using the procedure described in the ASTM D7 6661-10 method and the ARDL method. JoyDrops® Natural Personal Lubricant Gel was found to be compatible with latex condoms, and polyisoprene and polyurethane condoms. This is the same as the statement made by Walgeens Personal Lubricant Jelly, which is the "substantially equivalent" comparison product.

Summary of test data that confirm that JoyDrops® Natural Personal Lubricant Gel is safe for use. 807.92(b)(3)]
JoyDrops® Natural Personal Lubricant Gel has been tested for safety by subjecting it to cytotoxicity testing, systemic toxicity testing, vaginal irritation testing, and sensitization testing.
1. The cytotoxicity tests were conducted using the ISO 10993 methodology. No cellular toxicity was found.
2. The systemic toxicity testing was conducted using a standard protocol developed by NAMSA, and approved by FDA upon submission. No systemic toxicity was found.
3. Vaginal irritation was studied using the International Organization for Standardization 10993-10, Biological Evaluation of Medical Devices. The test article was considered a nonirritant to vaginal tissue.
4. Skin sensitization patch tests in humans and skin sensitization tests in animals were conducted according to standard practices, including ISO 10993-10/AI. No skin sensitization was reported.
These tests are consistent with the expectations of this class of device, and are substantially equivalent to the predicate product.

Biocompatibility

Test	Result
***In Vitro* Cytotoxicity**	**No Cytotoxic Effects Seen**
Skin Irritation (Human Patch Test) 30 minutes	**No Skin Irritation was Observed**
Skin Irritation (Human Patch Test) 24 hours	**No Skin Irritation was Observed**
Skin Sensitization - Animals (Guinea Pigs); 3 Weeks	**No Skin Sensitization was Observed**
Vaginal Irritation (Rabbits)	**No Irritation Observed**
Systemic Toxicity	**No Mortality or Evidence of**

(Mice); 7 Days	**Systemic Toxicity**

The test sample extract was prepared according to ISO 10993-12, Table 1 “Standard surface areas and extract liquid volumes”. Since the test sample is irregularly shaped solid devices (powder, pellets, foam, non-absorbent molded items) 0.2 g/ml extraction ratio was used. In order to use diluted extract of sample, 0.1 g/ml extraction ratio was also used. According to ISO 10993-12; 10.3.5 Extraction using both polar and non-polar extraction vehicles were performed.

The supplementation of basal culture media with animal serum of different origins is essential for cell growth, metabolism, and to stimulate proliferation (“mitogenic effect”). The major functions of serum in culture media are to provide (i) hormonal factors stimulating cell growth and proliferation and promoting differentiated functions, (ii) transport proteins carrying hormones (e.g. transcortin), minerals and trace elements (e.g. transferrin) and lipids (e.g. lipoproteins), (iii) attachment and spreading factors (Brunner et al., 2010, Altex 27; 1/10).

In order to support cell growth, 5% FBS was used until it was approximately 50% confluent. By adding extract of test materials the FBS concentration was decreased to 1% in order to continue cell growth and avoid cells to be overexposed to hormonal and growth factors according to the basic cell culture knowledge, since the percentage of the FBS has not been mentioned in the standard. According to our procedure, the extract condition includes 1% FBS.

The product is expected to be in contact with vaginal epithelial cells for less than 24 hours.

Packaging

JoyDrops® Natural Personal Lubricant Gel is packaged in 100 mL plastic polymer bottles. The bottle has a dispensing nozzle which in turn is covered by a plastic cap. The plastic cap has a tamper-resistant covering which must be removed in order to apply the gel. The bottle has a wrap-around label that meets the requirements of the FDA’s labeling guidelines.

Technological Characteristics [807.92(a)(6)]:

Both the predicate device (Walgreens Personal Lubricating Jelly) and JoyDrops® Natural Personal Lubricant Gel have the same technological characteristics. They are both water-based gels that contain similar ingredients that allow vaginal lubrication and/or lubrication of condoms to ease the friction of sexual activity. Both lubricating gels are compatible with both latex-based condoms and common polymer-based condoms.

Substantial Equivalence [807.92(b)(1)]:

JoyDrops® Natural Personal Lubricant Gel is substantially equivalent to a marketed device: Walgreens Personal Lubricating Jelly. The intended use, active (lubricating) ingredients, presence of preservatives, and application of the proposed device are substantially equivalent to those of the predicative device. Both products are/will be sold over-the-counter and are indicated as personal lubricants.

	JoyDrops® Natural Personal Lubricant Gel	Walgreens Personal Lubricating Jelly
Manufacturer	**Turkuaz**	**McNeil-PPC Inc**
Intended use	**Personal lubricant**	**Personal lubricant**
Application	**Topical**	**Topical**
Over the counter use	**Yes**	**Yes**
Labeled water soluble	**Yes**	**Yes**
Labeled "condom compatible"	**Yes**	**Yes**
Contains Glycerin (Wetting Agent)	**Yes**	**Yes**
Contains Hydroxyethylcellulose (Gel	**Yes**	**Yes**
Contains Preservative and Buffering Ingredients	**Yes**	**Yes**
Contains alcohol	**No**	**No**
Contains fragrances	**No**	**No**
Container material	**Plastic Polymer**	**N/A**
Sterile	**No**	**No**

Product Characteristics

The primary characteristics of Joy Drops® Natural Personal Lubricant Gel include:

☐Lubricating agent
☐Adjusted to a pH of ≈ 7.0
☐Water soluble
☐Chemically preserved to insure freshness
☐Non-sticky
☐Gel consistency
☐Does not contain lipids
☐Does not contain formaldehyde and salt
☐Does not have fragrance or odor

Ingredients and Specifications

Ingredients	Quantity (W/V%)	CAS Number	Supplier
Hydroxy Ethyl Cellulose	1.0-2.0	9004-62-0	Dow Chemical
Glycerin	12.0-17.0	9004-62-0	So Gis Industria Chimica Spa Italy
Mono Propylene Glycol	1.0-5.0	57-55-6	Sigma Aldrich Germany
Citric Acid	0.01-0.1	77-92-9	Sigma Aldrich Germany
Phenoxyethanol & Ethylhexylglycerin	0,05-0.2	122-99-6/70445-33-9	Sigma Aldrich Germany/
Deionized water	q.s 100	7732-18-5	

Packaging
JoyDrops® Natural Personal Lubricant Gel is packaged in 100 mL plastic bottles with a dispensing nozzle and plastic cap.

Stability 807.92(d)]:
JoyDrops® Natural Personal Lubricant Gel was placed in temperature control cabinets set at 22^{o}C and 60^{o}C. Based on the data obtained by an independent laboratory, a shelf-life of three years was established. Based on the data, microbiological specifications were set at <10 cfu/mL-g.

Software
There isn't any computer software that is required for the application of this product.

EMC and Electrical Safety
The device does not require EMC and Electrical safety evaluation.